

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DISVISION AT COOKEVILLE**

ANDREW SCOTT RODRIGUEZ,

Plaintiff,

vs.

STRYKER CORPORATION, a Michigan

Corporation; STRYKER SALES
CORPORATION, a Michigan corporation,

Defendants.

C.A. No. 2:08-cv-124

JUDGE ALETA A. TRAUGER
MAGISTRATE BRYANT

JURY DEMAND

**REPLY BRIEF IN SUPPORT OF MOTIONS TO EXCLUDE
SUZANNE PARISIAN, M.D. AND YADIN DAVID, Ed.D.**

Defendants Stryker Corporation and Stryker Sales Corporation (collectively “Stryker”) file this Reply Brief in Support of their Motions to Exclude Suzanne Parisian, M.D. and Yadin David, Ed.D. as follows:

SUMMARY OF ARGUMENT

Plaintiff’s regulatory experts propose to testify about FDA regulations and Stryker’s compliance with them. Stryker pointed out numerous reasons why the Court should prohibit that testimony, including:

- (1) Under *Buckman* and 21 U.S.C. § 337(a), private parties may not enforce FDA regulations.
- (2) Under *King* and *Bish*, FDA regulations are irrelevant to the standard of care in Tennessee.
- (3) Under *Torres*, the Sixth Circuit prohibits expert testimony about the law.
- (4) Under *Buckman*, federal law does not require device makers to warn about “off label” use, *i.e.*, about what indications the FDA has declined to approve (which contradicts Plaintiff’s proposed testimony).

In response, Plaintiff merely tries to distinguish these cases. The Court should reject that effort. Most importantly, *Buckman* is not limited to “fraud-on-the-FDA” claims. It

broadly prohibits private enforcement of the FDCA. Thus, *Buckman* prohibits just the sort of attack on Stryker's regulatory compliance that Plaintiff's experts are making. As to *King* and *Bish*, Plaintiff fails to challenge the principles that animated those decisions. They leave no doubt that FDA compliance is irrelevant to the standard of care.

As to *Torres*, Plaintiff claims that experts can testify about the law—but only when those legal issues do not appear on the jury charge. However, this argument is self-defeating. It merely confirms that the regulations are irrelevant. Finally, Plaintiff completely ignores that his experts are attempting to blame Stryker for violating a *regulatory duty that does not exist*. Federal law does not require manufacturers to warn about “indications” that the FDA has declined to approve.

Stryker will also address two other issues that are common to Drs. Parisian and David: the effect of Dr. Kuhn's testimony and TENN. CODE ANN. § 29-28-104 on their testimony. Then, after addressing the common issues, Stryker will turn to the unique issues raised by Drs. Parisian and David individually.

I. Under *Buckman*, *King*, and *Bish*, Dr. Parisian's and Dr. David's Testimony Is Irrelevant and Prejudicial.

As Plaintiff notes, many of Stryker's arguments apply equally to both Drs. Parisian and David. Stryker will address those common issues before proceeding to the individual issues with each expert.

A. Plaintiff's Proposed Attack on Stryker's Regulatory Compliance Would Violate *Buckman*.

Plaintiff first tries to limit *Buckman* to one narrow holding: that it only prohibits fraud-on-the-FDA claims. Plaintiff's Consolidated Opposition to Defendant Stryker's Motions to Exclude Plaintiff's Experts (“Response”) at 61-62. This argument is baseless. Instead of being limited, *Buckman* is based on a statute that limits enforcement of *any* aspect of the Food

Drug and Cosmetic Act (“FDCA”) to the federal government. *See* 21 U.S.C. § 337(a) (“[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.”). The Supreme Court was explicit about the importance of this statute:

In the present case, by contrast, we have clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government. 21 U.S.C. § 337(a).

Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 352 (2001).

Thus, it is Congress itself that broadly prohibits Plaintiff from acting as a private attorney general to enforce the FDCA. *See In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (“In *Buckman* ... the Court construed § 337(a) as barring suits by private litigants ‘for noncompliance with the medical device provisions.’”).

Moreover, *Buckman* was motivated by the effect that “50 States’ tort regimes” would have on the FDA’s regulation of manufacturers:

[C]omplying with the FDA’s detailed regulatory regime in the shadow of 50 States’ tort regimes will dramatically increase the burdens facing potential applicants

Id. at 350 (emphasis added). Similarly, here, Plaintiff’s attack on Stryker’s regulatory compliance creates an impermissible burden on Stryker’s distribution of its FDA-approved devices to patients. In short, the Court would create a precedent that may require Stryker to prove its FDA compliance to juries across the country.

In addition, subjecting Stryker to potentially inconsistent verdicts across the country would hinder the FDA’s advancement of its “difficult (and often competing) objectives.” *See Buckman*, 531 U.S. at 349-50; *see also Lewkut v. Stryker Corp.*, -- F. Supp. 2d --, 2010 WL 1544275, *8 (S.D. Tex. April 16, 2010) (“[C]ourts have held that that private enforcement of

FDCA regulations via state common law would interfere with this regulatory scheme and is therefore prohibited.”) (citing *Buckman*).

Finally, Plaintiff claims that he does not assert fraud-on-the-FDA claims. Yet Plaintiff’s experts openly attack Stryker’s compliance with the FDA’s reporting requirements. *See, e.g.*, Report of Suzanne Parisian, M.D, (“Parisian Rpt.”) at 6, attached as Exhibit B to Memorandum of Law in Support of Motion to Exclude Suzanne Parisian, M.D. (“Memo. to Mtn. To Exclude Parisian”) (“Stryker failed to adequately monitor and warn physicians and FDA about risks associated with postoperative continuous intra-articular infusion.”); Report of Yadin David, Ed.D. (“David Rpt.”) at 2-3, attached as Exhibit B to Memorandum of Law in Support of Motion to Exclude Yadin David, Ed.D. (“Memo. to Mtn. to Exclude David”) (asserting, in **Opinion #4**, that Stryker failed to properly report patient injuries); Deposition of Yadin David (“David Depo.”) at 108-09, attached as Exhibit A to Memo. to Mtn. to Exclude David (asserting that the alleged improper reporting violated federal law).

Under *Buckman*, these are disguised fraud-on-the-FDA claims. Specifically, *Buckman* identified a claim that attacks compliance with FDA “reporting requirements” as a fraud-on-the-FDA claim. *See Buckman*, 531 U.S. at 350-51. In fact, the heart of Dr. Parisian’s opinions is her allegations about what Stryker knew and what FDA did not know—because Stryker was supposedly hiding information. *See Parisian Rpt.* at ¶ 111 (“[N]one of Dr. Paulos[’] 2005 reports for patients with chondrolysis for patients of Dr. Paulos, Andrew or Savoie resulted in MDRs filed with FDA”); *Id.* at ¶ 128 (“Dr. Beck’s 13 patient complaints of chondrolysis should have been present in Stryker’s complaint data system as open complaints being investigated as to reportability for filing of MDRs.... [Doing so] could have provided FDA’s investigator with an opportunity to follow-up to obtain additional safety information”).

B. FDA Regulations Are Not Part of the Standard of Care.

Aside from *Buckman*, these FDA regulations are not relevant to the standard of care. See *Bish v. Smith & Nephew Richards, Inc.*, 2000 WL 1294324, *5 (Tenn. Ct. App. Aug. 23, 2000) (attached as Exhibit C to Memo. to Mtn. to Exclude David); *King v. Danek Medical, Inc.*, 37 S.W.3d 429, 457 (Tenn. Ct. App. 2000). Thus, there is no “fit” between what the experts intend to prove (regulatory violations) and what Plaintiff must prove at trial (that the products were “defective or unreasonably dangerous at the time they left the manufacturer’s control”). *United States v. Bonds*, 12 F.3d 540, 555 (6th Cir. 1993); *Bish*, 2000 WL 1294324, at *5. Thus, the proposed testimony would merely create an irrelevant sideshow at trial.

Plaintiff attempts to distinguish *Bish* on various grounds. See Response at 62-63. But there is no question that any fair reading of the opinion shows that *Bish* held that the regulatory testimony was irrelevant. See 2000 WL 1294324, at *5 (“[T]he evidence excluded by the trial court ... does not tend to prove the determinative issues in the case”). Surprisingly, Plaintiff even argues that *Bish* actually found the regulatory evidence relevant—but excluded it solely under Rule 403. But the plain language of the opinion contradicts this argument. See *id.* (“Under the state of this record, if there is any probative value to the testimony, it is substantially outweighed by the dangers outlined in Rule 403.”) (emphasis added). Moreover, Rule 403 applies to this case. So the Rule 403 holding in *Bish* is just as persuasive here as the relevance holding.¹

Plaintiff likewise tries to distinguish *King* on the basis that it was evaluating whether to recognize a negligence *per se* claim. See Response at 64. But this argument ignores

¹ Plaintiff cites *Richardson v. Miller* to show that Tennessee supposedly allows testimony about FDA regulations. 44 S.W.3d 1, 16 (Tenn. Ct. App. 2000). But that opinion merely allowed testimony about “off label” use of a drug to evaluate a *doctor’s* standard of care. See *id.* at 15-17. The evidence had nothing to do with regulatory compliance. See *id.*

the Court's reasoning. *King* held that the FDA regulations at issue could not support a negligence *per se* claim because those regulations did not create a standard of care:

The plaintiffs have not even attempted to show that the statutes upon which they base their negligence *per se* claim set out other than administrative requirements.

King, 37 S.W.3d at 457. Moreover, the regulations at issue in *King* included the same “misbranding” and “adulteration” provisions at issue here because the plaintiff in *King* (like experts here) alleged “that the defendants marketed their device for a use not approved by the FDA.” *Id.* at 456; *see also id.* at 454-55 (listing the “misbranding” and “adulteration” provisions at issue in *King*).²

Plaintiff also tries to avoid *King* and *Bish* with a slight-of-hand. He implies that a “prudent” manufacturer would have followed all FDA regulations. *See* Response at 80-81; *see also id.* at 61 & 63. In other words, he claims that following federal regulations is inherently “prudent” and thus, by definition, part of the standard of care (or part of industry practice). But this argument ignores the holdings of *King* and *Bish*. They held that safety is simply a different issue than regulatory compliance. *See, e.g., King*, 37 S.W.3d at 458 (“The plaintiffs failed to analyze these FDCA statutes and demonstrate that they impose a standard of care”).

C. Plaintiff Cannot Avoid the Sixth Circuit's Prohibition on Expert Testimony About the Law.

Plaintiff also tries to avoid the Sixth Circuit's prohibition on expert testimony about the law by citing to a footnote in a decision by the Southern District of New York. *See* Response at 71 (citing *In re Fosamax Products Liability Litig.*, 645 F. Supp. 2d 164, 191 n.16

² Nor do Plaintiff's cases stand for the proposition that FDA regulations establish the standard of care in Tennessee (or in Kentucky, which was the jurisdiction at issue). *See, e.g., Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 538 (6th Cir. 1993) (evaluating pre-emption claims against pharmaceutical drugs, not pharmaceutical devices).

(S.D.N.Y. 2009)). Specifically, *Fosamax* applied an exception to this principle when (1) the experts would not address the law that “governs the case” but nevertheless (2) their legal testimony would be relevant to whether the manufacturer acted prudently. *See Fosamax*, 645 F. Supp. 2d at 191 n.16.

Under *Erie* principles, this holding does not apply in Tennessee. Under *Bish* and *King*, compliance with federal regulations is not relevant to the standard of care. *See Bish*, 2000 WL 1294324, at *5; *King*, 37 S.W.3d at 457. So the second condition in *Fosamax* is absent.

Moreover, the internal logic of the footnote in *Fosamax* is inconsistent. If federal regulations determine whether a manufacturer acted prudently, then, by definition, they define the standard of care—and thus govern the case. Plaintiff cannot have it both ways. Either the regulations define the standard of care, in which case the Court has exclusive responsibility to determine the law. *See Torres v. County of Oakland*, 758 F.2d 147, 150-51 (6th Cir. 1985). Or the regulations are irrelevant to the standard of care.

Finally, Plaintiff ignores the fact that his experts get the law wrong. *See id.* at 150. Stryker will address an example of that next.

D. Plaintiff’s Experts Are Wrong on the Law—There Is No Duty to Warn Doctors about “Off Label” Use.

Plaintiff did not respond to Stryker’s argument that his proposed regulatory testimony is based on a legal mistake. According to Plaintiff’s experts, Stryker had a duty to warn doctors that the FDA declined to approve an “indication” for the pain pump. In other words, federal law supposedly required Stryker to discourage the use of the device for this proposed indication—*i.e.*, for this “off label” use.

The opposite is true. *Buckman* itself emphasized that “off label” use is permissible and valuable. *See Buckman*, 531 U.S. at 350-51. The facts in *Buckman* directly

raised the issue of “off label” use. *See Buckman*, 531 U.S. at 344 & 346-47 (plaintiff injured by the use of a device for a purpose that the FDA had previously rejected). Given those facts, the Supreme Court *specifically* held that state tort law should not interfere with FDA’s efforts to ensure that doctors have the freedom to prescribe “off label”:

Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability.

Id. at 350; *see also Richardson v. Miller*, 44 S.W.3d 1, 12 (Tenn. Ct. App. 2000) (“To avoid limiting the ability of physicians to treat their patients, the lack of FDA approval of a drug or device for a particular use does not imply that using the drug or device for that use is either disapproved or improper.”) (citations omitted).

Thus, *Buckman* explicitly rejected the legal premise at the heart of Plaintiff’s proposed expert testimony.

E. The Treating Physician’s Testimony Makes the Regulatory Testimony Irrelevant.

Another issue that affects the admissibility of both Drs. Parisian and David is the undisputed testimony from the treating doctor that:

- (1) He does not recall reviewing Stryker’s “instructions for use”;
- (2) He does not normally review “instructions for use” if he is familiar with a device;
- (3) He was thoroughly familiar with the pain pump by the time of Plaintiff’s surgery;
- (4) His initial decision to use pain pumps was based on medical literature, not on any communication with Stryker; and
- (5) He does not recall speaking with any sales people from Stryker when he was learning to use pain pumps.

See Deposition of John E. Kuhn, M.D. (“Kuhn Depo.”) at 13-18, 21, 55, 57 & 62-63, attached as Exhibit G to Memo to Mtn. to Exclude Parisian. Under Tennessee law, this evidence destroys the causal link between the warnings and the injury (as well as between any communications with Stryker and the injury). See *King*, 37 S.W.3d at 453.

Plaintiff’s Response does not challenge the fact that Dr. Kuhn would not have read any revised “labeling”—which confirms that Stryker’s warnings and “instructions for use” are irrelevant to this lawsuit. See Response at 65. Instead, Plaintiff claims that Stryker should have communicated directly with doctors through other means. See *id.* (suggesting that Stryker should have used direct mailings, presentations at professional meetings, letters to doctors, warnings on the device itself, and sales representatives).

However, FDA-approved “labeling” is supposed to be the focal point of a manufacturer’s safety efforts:

The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for a prescription drug, because such labeling is FDA’s principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use.

71 Fed. Reg. 3922-01, at *3934, 2006 WL 160271 (emphasis added).

In light of the importance of the labeling, Plaintiff’s experts are essentially suggesting that Stryker should have undertaken an extraordinary effort beyond issuing proper warnings. The experts have not justified such dramatic measures. For example, they have not explained what types of threats to public safety normally justify such a communication campaign. In short, their opinion is based on little more than the experts’ “say so.” See *General*

Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (“[N]othing ... requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”).

Nor have these experts demonstrated sufficient expertise to justify this unusual opinion. Neither Dr. Parisian nor Dr. David indicate that they have ever participated in such a campaign. This is particularly important given that Plaintiffs justify their “non-scientific” testimony on their alleged experience. Response at 61 (“Mr. Rodriguez’s non-scientific experts have ‘seen a lot more bumblebees’ than the jury”).

F. The Rebuttable Presumption under Tennessee Law Does Not Permit Plaintiff to Violate Buckman and 21 U.S.C. § 337(a).

Plaintiff next invokes TENN. CODE ANN. § 29-28-104 to defeat *Buckman* and 21 U.S.C. § 337(a). The obvious problem with this argument is the Supremacy Clause. Even if Plaintiff’s interpretation of Section 29-28-104 is correct, Congress has determined that a private party cannot enforce FDA regulations. See 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 352. This pre-empts any state law that purports to allow Plaintiff to prosecute Stryker for violations of the FDCA—because Tennessee has no interest in the relationship between the FDA and Stryker. See *Buckman*, 531 U.S. at 347 (“[T]he relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.”).

In addition, Plaintiff misinterprets Section 29-28-104. It does not allow Plaintiff to make a case against a pharmaceutical manufacturer on the basis of alleged FDA violations. It is a *defensive* statute that reflects a legislative decision to subordinate Tennessee tort law to government agency decisions. In this case, the FDA has not engaged in any enforcement action against Stryker to indicate that it agrees with the Plaintiff’s experts. See David Depo. at 80-81.

Thus, it would turn Section 29-28-104 on its head to allow Plaintiff to invoke it to justify his attack on Stryker's regulatory compliance.

Finally, the proposed expert testimony exceeds the bounds of Section 29-28-104. That statute creates a presumption in favor of a manufacturer who complied with statutes or regulations governing the “[1] design, [2] inspection, [3] testing, [4] manufacture, [5] labeling, [6] warning or [7] instructions for use of a product.” TENN. CODE ANN. § 29-28-104. In contrast to this list, Plaintiff's experts assert that Stryker violated the FDA's *reporting* requirements and should have undertaken a special communication campaign instead of merely updating its ordinary labeling, warnings, and instructions for use.³

II. The Court Should Follow Other Courts in Limiting or Excluding Dr. Parisian's Testimony.

Much of Plaintiff's Response addressed the unique problems with Dr. Parisian's proposed testimony. Plaintiff offers several cases in which Dr. Parisian has been allowed to testify, some of which Stryker previously cited. Nevertheless, it is striking that even the decisions cited by Plaintiff limit Dr. Parisian's opinion in some manner. This is an indication of just how controversial her *modus operandi* really is.

A. Dr. Parisian's Testimony on FDA Compliance Is Improper and Irrelevant.

One of these opinions is *Lillebo v. Zimmer, Inc.*, 2005 WL 388598 (D. Minn. Feb. 16, 2005). Response at 70. The discussion in *Lillebo* is particularly on point—Plaintiff is emphatic in his Response that he has not made a claim of negligence per se, and in *Lillebo*, the plaintiffs made the same argument. The *Lillebo* court expressed concern that allowing Dr.

³ To the extent that Plaintiff is attacking the labeling, that would directly contradict the FDA's decision to approve that labeling. Normally, government approval of warnings is enough to invoke the presumption. *See, e.g., Goins v. Clorox Co.*, 926 F.2d 559, 561-62 (6th Cir. 1991) (invoking the presumption under Section 29-28-104 for EPA-approved warning labels). The Court should not interpret Section 29-28-104 to allow Plaintiff to challenge the FDA's decision to approve the labeling.

Parisian to testify about “the FDCA’s and FDA’s cumbersome and complex standards and offer an opinion as to [the device manufacturer’s] violation of these standards will improperly convert plaintiffs’ ordinary negligence claim into a de facto claim of negligence per se.” *Id.* at *5. The court articulated that because negligence and negligence per se claims are distinct in that the latter is for breach of a statutory duty, a discussion of noncompliance with a statute will confuse the issues. Consequently, the Court held that Dr. Parisian could not testify “concerning the specific legal requirements of the FDCA and FDA regulations and whether or not [the device manufacturer’s] actions comply with those requirements.” *Id.* The Court went on to allow Dr. Parisian to testify, narrowly—she was allowed to testify on “the general nature of the approval and regulatory process” and the manufacturer’s actions with respect to that. *Id.*

Plaintiff also offers *Reece v. AstraZeneca Pharms., LP*, 500 F. Supp. 2d 736, 744 (S.D. Ohio 2007) (Response at 71), but again, Dr. Parisian’s opinion was limited by the court. After examining her testimony on similar subject-areas to the case at hand, the *Reece* court allowed Dr. Parisian to testify regarding background information on the FDA approval and regulatory process and a manufacturer’s role within that context—she did not testify beyond the general nature of FDA procedures and regulations. *Id.* The court also excluded her testimony on medical causation and failure to warn because Dr. Parisian “failed to demonstrate that she used scientifically valid methodology or reasoning in reaching her conclusions on these matters.” *Id.* at 745. The court stated, “Dr. Parisian’s [causation] opinions were developed solely for the purposes of testifying at the trial of plaintiff’s claims . . . [a]s such, Dr. Parisian’s testimony is not reliable and will not assist the trier of fact in understanding and disposing of the issues.” *Id.*

Plaintiff further adds that Dr. Parisian has been allowed to testify in other pain pump litigation cases. However, Dr. Parisian’s testimony has been narrowed in this litigation as

well. For example, in the most recent trial, *McClellan v. I-Flow*, No. 07-CIV-1309-AA (D. Or. September 10, 2010), although Dr. Parisian was able to testify about FDA regulations, the court prohibited her “from testifying that a legal duty was created or violated, or that legal liability resulted from certain conduct.” Judge Ann Aiken’s September 10, 2010 Order at 1, attached as **Exhibit 1**. The Judge further limited her testimony by excluding “testimony constituting legal conclusions or legal instruction.” *Id.*

Here, Dr. Parisian’s proffered testimony should be similarly excluded, consistent with *Buckman*, *Bish*, *King*, and *Torres*. Dr. Parisian’s proffered testimony outlines over 15 FDA regulations, making unsupported bold conclusions that Stryker has violated or not complied with these regulations, and then gives a narrative of the regulatory and development history of Stryker’s pain pump. Dr. Parisian goes beyond discussing general background information on the FDA process or even Stryker’s review, and enters the province of the court by instructing the jury on the litany of FDA regulations that Stryker has supposedly failed to comply with. *See Torres v. County of Oakland*, 758 F.2d. 147, 150 (6th Cir. 1985). This testimony is improper, irrelevant, and will serve to confound the jury as to Tennessee law and Plaintiff’s negligence claim. Further, Dr. Parisian’s statements will be particularly confusing to the jury in that her conclusions are contrary to FDA’s treatment of Stryker’s pain pump. There is no evidence, offered by any party or Dr. Parisian, that FDA has taken any action against Stryker for any of the alleged transgressions. To the contrary, Dr. Parisian has testified that FDA has never taken any enforcement action against Stryker as to the pain pump; specifically, it has never required Stryker to modify its pain pump label. *See* June 4, 2010 Deposition of Suzanne Parisian, M.D. at 26:8-13 & 47:19-25, attached as Exhibit A to Memo. to Mtn. to Exclude Parisian.

The Court has the benefit of prior opinions examining Dr. Parisian's proffered testimony on regulatory matters, including those offered in Defendants' Memorandum of Law in Support of its Motion to Exclude Suzanne Parisian, M.D. These decisions offer guidance in dealing with Dr. Parisian's overly broad opinion. As such, the Court should similarly exclude Dr. Parisian's testimony.

B. Dr. Parisian's Regulatory Testimony Does Not Meet the Rigors of Rule 702 and *Daubert*.

At times, courts have allowed Dr. Parisian to give broader FDA testimony but still found that her testimony had to be reined to comply with *Daubert*. Commonly, Dr. Parisian is noted to morph from expert to plaintiff's advocate once she has made it onto the witness stand. *E.g., In re Trayslol*, 709 F. Supp. 2d 1323, 1347 (S.D. Fla. 2010). Dr. Parisian inundates the jury with a narrative and verbatim recitation of the defendants' internal documents and testimony, many times regarding the intent, knowledge, and actions of defendants and the FDA. Interestingly, Dr. Parisian does not link or provide analysis of her assertions of federal regulatory noncompliance with her "bad company" narrative. In an attempt to prevent this spectacle, the court in *In re Fosamax*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) limited Dr. Parisian's testimony by prohibiting her from presenting "a narrative of select regulatory events," regurgitating the evidence, testifying "as to the knowledge, motivations, intent . . . of Merck, its employees, the FDA, or FDA officials . . . , and providing "bad company testimony." *Id.* at 192. All of which is offered here by Dr. Parisian, as is outlined in her report. Parisian Rpt. *generally*. Dr. Parisian was further prohibited from testifying on the defendant's alleged failure of adequate disclosure because "she could not name any standard that prohibits such a practice." *Id.* at 191. Other courts have followed this lead. *See In Re Ingram v. Wyeth*, MDL No. 4:03CV01507-WRW (E.D. Ark. September 16, 2010) (excluding Dr. Parisian's testimony in its

entirety, and in so, stating that she failed to give an objective standard in offering what she believed defendants “could have done versus what they should have done). Judge Joe J. Volpe’s September 16, 2010 Order, attached as Exhibit H to Memo. to Mtn. to Exclude Parisian.

Plaintiff believes that the court in *In re Trayslol* and Stryker missed the boat in relying on *In re Prempro Products Liability Litigation*, 586 F.3d 547 (8th Cir. 2009) because the underlying district court’s opinion was post-trial. The Eighth Circuit in *In re Prempro* may have discussed the district court’s ruling to strike Dr. Parisian’s testimony after the liability portion of the trial. But the importance of the opinion is that both courts disclosed the problems inherent in allowing her to testify in the first place. 586 F.3d at 571. The district court stated that much of Dr. Parisian’s testimony was “simply read[ing] the contents of exhibits, thus undermining the asserted basis for expert testimony,” and not staying on “the topic of FDA guidelines.” 586 F.3d at 571. Taking the *In re Prempro* court’s warning to heart, the court *In re Trayslol* struck Dr. Parisian’s testimony in its entirety. See 709 F. Supp. 2d. at 1351. Despite the plaintiff’s counsel’s assertions, the judge did not believe that Dr. Parisian’s testifying manner would be any different. See *id.* (“Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702. . . .”). Dr. Parisian “generally takes a collection of facts, imputes motive and knowledge, and draws unsupported conclusions unrelated to any regulatory expertise.” *In re Trasylol*, 709 F.Supp. 2d 1347; see also *In re Guidant Corporation Implantable Defibrillators Products Liability Litigation*, 2007 WL 1964337 at *7-*8 (D. Minn. June 29, 2007) (prohibiting Dr. Parisian to opine on whether or not the manufacturer “violated” its warning requirement, indication and conditions of approval; and the manufacturer’s knowledge, intent and ethics) (attached at Exhibit C to Memo. to Mtn. to Exclude Parisian).

Plaintiff responds that Dr. Parisian will not do it again—“Dr. Parisian is not proffered to testify in narrative form and will not express any opinions on Stryker’s intent . . .”. Response at 73. But, this is not believable. And, indeed, Dr. Parisian’s report in this case foreshadows the testimonial “bad company” narrative that this Court is likely to hear. She walks the reader through the evolution of Stryker’s pain pump by reciting document after document, without giving analysis to support her conclusions. Also, in concluding that there has been noncompliance with FDA regulations, there is no discussion of FDA’s action with respect to the pain pump approval and surveillance process.

Dr. Parisian’s proffered testimony is irrelevant and lacks reliable methodology under *Daubert*, including the reasons more fully discussed in Defendant’s Memorandum to its Motion, and will not assist the jury in determining a fact at issue—the jury can read the evidence for themselves and then apply the appropriate Tennessee law with the instruction from the Court. See *U.S. v. Pollard*, 128 F. Supp. 2d 1104, 1124 (E.D. Tenn. 2001) (“the court must determine whether expert testimony will assist the jury in resolving a question of fact or whether such expert testimony will simply make the job of the jury more difficult”).

C. Dr. Parisian is Not Qualified to Testify on Liability and Causation.

Moreover, Dr. Parisian lacks the qualifications to give her proffered testimony on the regulatory aspects of pain pumps and related causation. Plaintiff tries to dismiss the decision in *Anderson v. St. Jude Medical, Inc.*, No. 00-CV-195906CP, because one of the reasons the court gives for striking Dr. Parisian is that an interpretation of U.S. law and requirements therefrom is not relevant in determining liability under Canadian law. Attached as Exhibit D to Memo. to Mtn. to Exclude Parisian; Response at 73-74. This is exactly the point Stryker is making as to the relevance of federal regulations in a Tennessee products case. Regardless, the

Anderson decision is broader than that. The *Anderson* court made several findings in striking Dr. Parisian's testimony, two of which were on her qualifications. First, Judge Lax stated that "Dr. Parisian's generalized knowledge during her two years as a medical officer with clinical responsibilities for the approval of other medical devices does not qualify her to offer an opinion about the approval or decision-making process for a different device in a different division of the Office of Device Evaluation." *Id.* at 474. The subject of that case was heart valves, and as with pain pumps, Dr. Parisian had performed no work or had any responsibilities over heart valves while she was at FDA. *See id.* at 469-474. In ruling that she was unqualified, he expressed that any opinion that Dr. Parisian could offer on FDA practices would not assist the court. *Id.* at 474. Judge Lax further found Dr. Parisian unqualified to give testimony on post-approval compliance with FDA requirements. *Id.* at 475-477 (" . . . [H]er role at FDA did not entail providing legal opinions She is not qualified to provide expert evidence to assist the court with proving the content of U.S. law or opining on the interpretation of these laws so as to conclude that [the device manufacturer] was in violation of the U.S. FDCA regulations").

Dr. Parisian was with the FDA for a limited time, and was not in the department that had responsibility over orthopedic devices nor did she perform any work related to pain pumps—she was not part of the review, development, or labeling and approval process. *See 3/2/09 Grossnickle v. Stryker* trial transcript at 924:21-24, attached as Exhibit K to Memo. to Mtn. to Exclude Parisian. Furthermore, Dr. Parisian has no experience in orthopedics as a practicing physician. *Id.* at 897:5-8. She possesses no specialty outside of pathology, besides her career as a litigation consultant. Consequently, the only experience she has with pain pumps is from this litigation and as such, is unreliable under *Daubert*. The Court should exclude Dr. Parisian's proffered testimony on Stryker's purported regulatory violations and on the alleged

chondrolysis from use of Stryker's pain pump, to the extent that far-reaching testimony enters causation, based on the foregoing reasons and her qualifications.

D. Events That Occurred After Plaintiff's Surgery Are Irrelevant.

Dr. Parisian has been offered as an expert on the liability of Stryker with respect to its pain pump; however, Plaintiff now is trying to slide in evidence through its expert that cannot be used to prove liability in this case. Dr. Parisian's report covers a wide range of time and events, including those after Plaintiff's surgery in this case. Parisian Rpt. at 30-65. Plaintiff's surgery occurred on November 15, 2004. Therefore, any subject matter in Dr. Parisian's report regarding events that occurred after this date is irrelevant and should be excluded. *See In re Fosamax*, 645 F. Supp. 2d at 192; *Osborne v. Pinsonneault*, 2009 WL 1046008 at *5 (W.D. Ky. Apr. 20, 2009) (attached as Exhibit I to Memo. to Mtn. to Exclude Parisian). Dr. Parisian should be focused on the relevant inquiry for liability—What did Stryker know at the time of Plaintiff's injury, November 2004? TENN. CODE ANN. § 29-28-105(b).

Other courts have dealt with this problem with Dr. Parisian's proffered testimonial content before. *In re Fosamax*, 645 F. Supp. 2d at 192. The court in *In re Fosamax* determined that "Dr. Parisian's report discusses events occurring over a wide span of time. The portions of her testimony relevant in any particular case likely will depend on the dates of the plaintiff's alleged ingestion of Fosamax and onset of ONJ. Thus, transferor courts will have to determine what portions of her testimony fit the facts of the specific cases before them." *Id.*; *see also U.S. v. Pollard*, 128 F. Supp. 2d at 1116 (citing *U.S. v. Bonds*, 12 F.3d at 555) (the *Daubert* relevance requirement directs that there be a "fit" between the testimony and the issues to be resolved at trial). Consequently, subject matter related to events occurring after Plaintiff's

surgery must be excluded as irrelevant. *Id.*; *Osborne*, 2009 WL 1046008 at *5 (conduct after alleged negligent event has no bearing on negligence claims).

However, Plaintiff responds that Dr. Parisian's testimony that may be irrelevant and improper as to liability goes to punitive damages. This argument is misplaced and not persuasive. Plaintiff is attempting to slip in irrelevant factual information through the back door, under the guise of expert testimony. *Metcalfe v. Waters*, 970 S.W.2d 448, 452 (Tenn. 1998), was a legal malpractice case that was specifically examining whether the concealment of wrongdoing that occurred after the alleged malpractice can be evidence of punitive damages. However, *Metcalfe* only discussed the applicability of post-injury facts in the context of concealment of wrongdoing—the Court did not go beyond the facts of that case to make a general finding as to all later acts as Plaintiff suggests. In fact, later courts have articulated that the holding in that case was specific to the facts at issue, concealment of wrongdoing. *See Stewart Title Co. v. First Am. Title Ins. Co.*, 44 F. Supp. 2d 942, 964 (addressing the Court in *Metcalfe's* holding specifically as to concealment of wrongdoing); *see also Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 543-44 (Tenn. 2008) (finding that trial court erred in admitting evidence of post-sale incidents, even in light of punitive damages claim).

Regardless, this factual testimony, purportedly for punitive damage purposes, is not proper for an expert under Rule 702, and more specifically an expert on liability claims. This testimony is clearly prejudicial in that it would be impossible for the jury to disregard it in discerning liability. FED. R. EVID. 403. This further could prove to be a moot issue as Stryker may move for bifurcation of that portion of the evidence.

III. Dr. David Lacks the Relevant Qualifications and His Testimony is Uniquely Unreliable.

Despite Plaintiff's Response, it is still clear that Dr. David lacks the necessary qualifications to testify about the topics he proposes to testify about—pain pumps, pharmaceutical warnings, and the FDA.

A. Plaintiff Misstates the Law.

Plaintiff first argues that *Daubert* is broad enough to allow testimony from experts like Dr. David who do not have specific expertise in the relevant area. *See* Response at 73 & 78-79 (arguing that *Daubert* gives courts “wide latitude” to allow expert testimony, even if the experts do not have “firsthand knowledge or observation”). But this is a misinterpretation of *Daubert*. That passage merely referred to the obvious proposition that experts can testify in cases in which they do not have firsthand knowledge of the facts. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 (1993) (“Unlike an ordinary witness, see Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.”).

When the Supreme Court mentioned that an expert has “wide latitude to offer opinions,” it was *not* referring to the expert's *qualifications*. *See generally id.* Thus, federal courts routinely exclude experts that lack qualifications in the relevant subject matter. *See Pride v. Bic Corp.*, 54 F. Supp. 2d 757, 761 (E.D. Tenn. 1998) *aff'd* 218 F.3d 566 (6th Cir. 2000) (excluding expert whose only experience with the product “consisted solely of his examination of and testimony concerning lighters in other Bic cases and viewing the manufacturing specifications for the J-6 lighter.”).

B. Dr. David Is Not a Pain Pump, Warnings, or FDA Expert.

Plaintiff next argues that Dr. David's experience acquiring medical products (including pain pumps) is sufficient to allow him to testify about all three topics—pain pumps, pharmaceutical warnings, and the FDA. Response at 77-78 (pain pumps); *Id.* at 79 (warnings and the FDA). But Dr. David repeatedly admitted that this work merely involved the administrative and bureaucratic supervision of others:

- **David Depo. at 53**—“[W]e have a very script process by which a product will be requested, submitted, review[ed] and evaluated by a task force or a committee that their responsibility will be to come up with a recommendation.” (emphasis added);
- **David Depo. at 62**—“My role would be to see that the process of evaluation throughout all this interdisciplinary participation follows a script” (emphasis added);
- **David Depo. at 63**—“[M]y role would -- would be such that I have to see that this process has been followed through time after time after time.”

Plaintiff simply ignores this testimony and proceeds as if that experience were relevant.

Plaintiff also emphasizes Dr. David's general engineering experience. *See, e.g.*, Response at 77 (“Dr. David has been a biomedical engineer for 30 years”); *Id.* at 78 (“Dr. David helped found the Healthcare Technology Foundation, which focuses on safety and training issues in healthcare.”). But general engineering expertise does not count as specific expertise about pain pumps, pharmaceutical warnings, or the FDA. *See Pride*, 54 F. Supp. 2d at 761 (“Dr. Sissom's general engineering expertise is clearly not particular to the science involved in this case”); *cf.* David Depo. at 51-52 (indicating that Dr. David has never been an FDA employee).

In his Response, Plaintiff claims that Dr. David has “familiarity” with “pain pumps specifically.” Response at 78. But even if “familiarity” were enough, the facts do not bear it out. David Depo. at 57 (indicating that, aside from his supervisory work as Director of

the Biomedical Department, Dr. David has not “ever evaluated a pain pump for any reason”) (emphasis added); *see also id.* at 63-64, 78, 84 & 127.

Finally, Plaintiff also relies on the fact that Dr. David’s sits on an advisory panel for the FDA to show his alleged experience with pharmaceutical warnings and the FDA. *See* Response at 79. But Plaintiff does not explain how sitting on that panel assures that Dr. David has specific expertise regarding the three relevant issues. Indeed, some of the members of the panel are merely consumers or patient advocates. *See* David Depo. at 122-23. Nor does Plaintiff show how Dr. David’s contract work with that panel gave him the relevant expertise. This is particularly important regarding his lack of warnings experience. Despite sitting on the panel, Dr. David has never written warnings for FDA-approved devices. *Id.* at 52. Nor has he ever been responsible for investigating or enforcing compliance with FDA warnings regulations. *Id.* at 51.

C. Dr. David Never Determined the Severity of the Risk.

Stryker also attacked Dr. David’s proposed testimony because he did not conduct a literature search to determine the magnitude of the risk. Nor did he confirm that Stryker had knowledge of the alleged risk at the relevant time. Stryker contended that, without that information, no expert could say that any particular warning (or course of action) would be medically necessary.

Despite this seemingly obvious proposition, Plaintiff insists that (1) the magnitude of the risk and (2) the manufacturer’s knowledge of that risk are irrelevant:

Dr. David is not Mr. Rodriguez’s causation expert, and Stryker skews the relevant inquiry, which is: whether Stryker acted as a reasonable and prudent manufacturer in light of [1] the lack of safety testing of its device and [2] the FDA’s rejection of a synovial cavity use indication.

Response at 79.

Quite frankly, this argument makes no sense. First, the FDA’s rejection of an indication does not dictate what warnings are necessary. *Cf. Richardson*, 44 S.W.3d at 12 (“[T]he lack of FDA approval of a drug or device for a particular use does not imply that using the drug or device for that use is either disapproved or improper.”) (citations omitted). Second, a critique of Stryker’s safety testing cannot produce a definitive answer about what Stryker’s warnings should have said.

In fact, as discussed above, Dr. David’s ultimate point is that Stryker should have undertaken *extraordinary* measures to warn about this particular risk—not merely to update its labeling. It is impossible for Dr. David to justify that opinion without knowing the magnitude of the risk.

D. Dr. David’s Opinion Largely Consists of Reciting Other Alleged Evidence—Often Incorrectly.

Finally, it appears that Plaintiff concedes that his regulatory experts should not provide narrative testimony. *See, e.g.*, Response at 72 (indicating that Rodriguez’s counsel has “no intention” of soliciting narrative testimony from Dr. Parisian).

In any event, Plaintiff does not contest that it is inappropriate for Dr. David to recite the factual testimony of other witnesses, most notably the testimony of Dr. Lonnie Paulos about “off label” promotion. Dr. David certainly has no “regulatory” basis to opine about whether Stryker promoted its products for “off label” use. *See* David Depo. at 81 (admitting that the FDA has never accused Stryker of off label promotion). Therefore, the Court should exclude such testimony.

Moreover, as Stryker pointed out originally, Dr. David’s testimony about off label promotion is irrelevant in light of Dr. Kuhn’s testimony that he did not rely on *any* conversations with Stryker’s sales representatives for his use of pain pumps. *See* Kuhn Depo. at 17-18 & 63.

CONCLUSION

In light of the above, Stryker respectfully requests that the Court exclude the testimony of Drs. Suzanne Parisian and Yadin David in their entirety.

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Respectfully submitted,

By: /s/ Gene M. Williams

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CERTIFICATE OF SERVICE

I hereby certify that on the 20th day of December, 2010, I electronically transmitted the foregoing document to the Clerk of the court using the ECF system for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

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